

REMARKS

New independent claim 17, together with dependent claims 18-28 have been newly added to the application by this Preliminary Amendment for consideration by the Examiner.

A minor change has also been made to page 13 of the specification to correct a grammatical error. The amino acid sequences in accordance with the present invention contain the concentration of one or more (i.e. mixtures) of the amino acid listed. The amino acid sequence of type III collagen is well known and determined. Several types of collagen have been identified to date and collagen is well documented in basic publications in the field of biochemistry. See, for example: Darnell et al., Molecular Cell Biology, pp. 906 (Scientific America Books 1990) (copy attached). Consequently, the amino acid sequence type III collagen molecule is a unique but easily determined molecule. Persons skilled in the art can obtain it from commercial sources in order to make the immunomodulator complex in accordance with the present invention.

It is submitted that the vaccine complex as set forth in claim 17 is described sufficiently in the specification such that persons of ordinary skill in the art could make and use it. The ribosomal ribonucleic acid is extracted from bacteria selected from the group consisting of: *Helicobacter pylori*, *Helicobacter hepaticus*, *Helicobacter coronari*, or mixtures thereof. The RNA's of ribosomal origin are described on pages 4-5 of the

specification, and methods for the preparation of RNA are mentioned on page 5 (lines 12-26).

The bacterial membrane fractions containing glycopeptides and/or lipopolysaccharides are widely described on pages 5-12 of the specification, including their sources and how they are produced.

The amounts and proportions of the components are given in detail on pages 20-22 and the efficiency of these compositions is shown in the examples on pages 22-24. Thus, it is submitted that the nature of the association between the components present in the complex and their optimal amounts are duly disclosed.

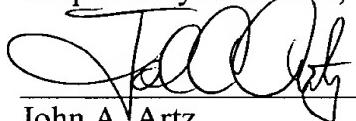
It is submitted that all of the components of the complex can be clearly determined by persons of ordinary skill in the art, who would be able to make and use the inventions with the help of the disclosed features combined with his/her professional knowledge in the field of the invention, without undue experimentation.

Finally, as to the subject matter of claim 12- which is now included in new claims 19 and 20 - it is submitted that "the production of antibodies" is consistent with the specification that states "the inefficacy" of the *Helicobacter* - specific antibodies in protecting an individual. Since the term "and" is used to join "the production of antibodies" and "the production of endogenous interferon," this indicates that the association of the complex components makes it possible to induce both humoral and cellular responses. This is consistent with the specification, page 3, lines 1-4: "the body

must produce in addition to the specific humoral immune response, a cellular response in order to make up for the inefficacy of the antibodies in protecting the individual" (emphasis added).

The Examiner is requested to consider the above Remarks when the new set of claims, namely claims 17-28, are considered and examined on the merits.

Respectfully submitted,



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**"VERSION WITH MARKINGS TO SHOW CHANGES MADE"**

**In the Specification:**

Page 13, lines 5-6 has been amended as follows:

a - Amino acid sequences [similar to] containing the following [sequence (the) concentrations [are] expressed in g/kg[]]:

**In the Claims:**

Claims 17-28 have been added.